

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2009 has been entered.

2. Claims 1-8 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1797

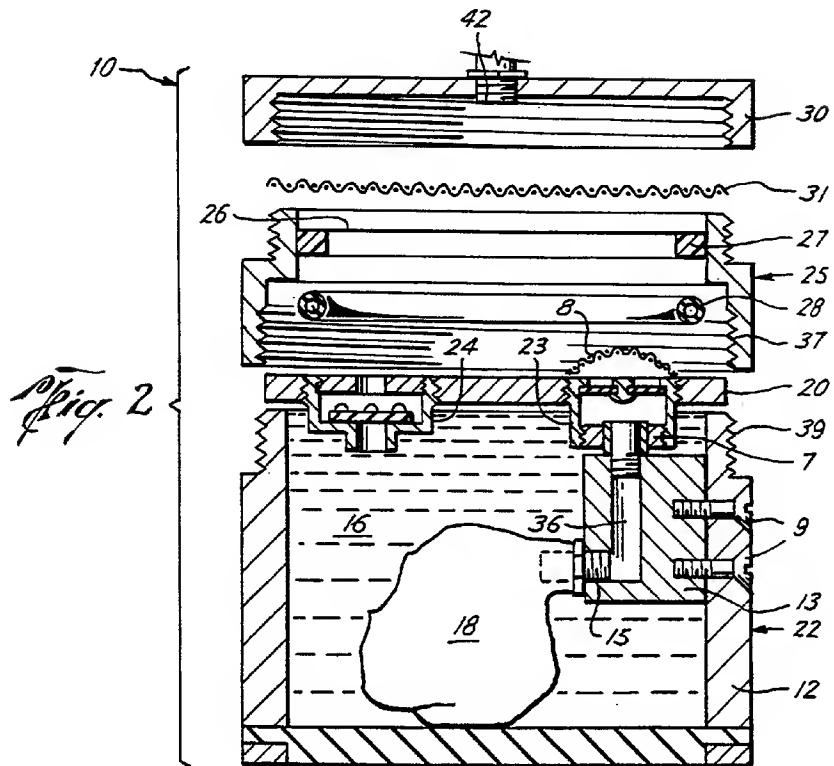
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by O'DELL (US 5385821).

a. With respect to claim 1, ODELL teaches a portable preservation apparatus of the cold storage type for a donor organ (Figure 2) comprising: a cooling box (cold storage unit) (Column 8, lines 36-46), a package (chamber with sidewalls)(Column 5, lines 21-24), an organ chamber in the cooling box (chamber 96) for receiving the package (tissue preservation device, 98) containing a donor organ in preservative fluid (Column 8, line 44-46, Figure 9); a lid (30) for the cooling box having a side which operatively faces the organ chamber (Column 5, lines 43-44); at least one perfusion pump (32) mounted at least partly in the lid of the package (Column 5, lines 44-46); a connector (22&25) detachably connected to the lid of the package (threaded attachment) (Column 7, lines 7-18) on the side of the lid which operatively faces the organ chamber, the connector and the package being arranged for removably and sealedly fastening

the connector to the package (Figure 2), which connector is provided with passages (valves 23, 24), one or more connecting pieces (36 &15) for connection with a donor organ in the organ chamber (Column 6, lines 65-67) and extending through one or more of the passages, and with one or more fluid pipes (25) connected with the at least one perfusion pump; at least one oxygenator (Column 3, lines 38-44); an oxygen container (Column 3, lines 20-21); one or more electronic modules and power supply module (Column 8, lines 7-16).

ODELL discloses the pump mounted and the connector connected to the part of the package lid (Figure 2) and doesn't explicitly disclose the pump and connector connected to the cooling box lid. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mount the pump and connect the connector to the cooling box lid, since it has been held that rearranging parts of an invention involved only routine skill in the art. *In re Japikse*, 86 USPQ 70 (CCPA 1950).



- b. With respect to claim 2, ODELL teaches the connector has the form of a container open on one side (25), and is provided with fastening elements (threading, latches, etc) which can cooperate with fastening elements provided to the lid for fastening the connector to the lid in such a detachable manner that the open side of the container faces the lid, while the passages are located in an otherwise closed wall (20) facing the organ chamber (Figure 2, Column 7, lines 7-18).

c. With respect to claim 3, ODELL teaches all part of the device coming into contact with preservative fluid are mounted in the connector, so that, together with the said at least one oxygenator, said at least part of the at least one perfusion pump coming into contact with the preservative fluid and said

corresponding fluid pipes, all mounted in the connector, the connector forms a single-use replacement part (Figure 2).

d. With respect to claim 4, ODELL teaches the at least one perfusion pump is a pump with a detachable driving motor (32), which driving motor is, in mounted condition, located on the side of the lid for the cooling box facing away from the connector and is connected with the remaining part of the pump via an opening in the lid for the cooling box, which remaining part of the pump is mounted in the connector (Figure 2). ODELL does not explicitly disclose the driving motor is detachably connected with the rest of the pump, however it would have been obvious to one of ordinary skill in the art at the time of the invention to make the motor detachable, since it has been held that construction a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicman*. 168 USPQ 177, 179.

e. With respect to claim 5, ODELL teaches the lid for the cooling box is provided with at least one of the one or more electronic modules (Figure 2).

f. With respect to claim 6, ODELL teaches the one or more electronic modules comprises a minicomputer (logic device) (Column 8, lines 7-16).

g. With respect to claim 8, ODELL teaches the outside of the connector, near the wall facing the organ chamber, the connector is provided with a number of circumferential grooves and or ribs for fastening an organ chamber (Figure 2, Column 7, lines 24-33).

Art Unit: 1797

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'DELL (US 5385821) in view of OWEN (US 6673594).

a. With respect to claim 7, ODELL teaches a cover on the lid (114) (Figure 9), but does not explicitly disclose this cover at least partly forms a window for a display screen of a minicomputer. However, OWEN teaches an organ perfusion apparatus in which an embodiment of the organ container has an inner and outer lid (cover) (Column 10, lines 41-42) that are construction of an optically clear material (window) (Column 10, lines 59-60). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of ODELL to include a window in the cover over the lid, as taught by OWEN because it allows for viewing the interior of the chamber to monitor the progress and status of the organ (Column 10, lines 60-63) and any other electronic components located inside the container without compromising the sterility of the organ.

Response to Arguments

8. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is

(571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1797

/William H. Beisner/
Primary Examiner, Art Unit 1797